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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,514	04/02/2001	Helke Lob	704018	8650
21324	7590	12/30/2003	EXAMINER	
HAHN LOESER & PARKS, LLP TWIN OAKS ESTATE 1225 W. MARKET STREET AKRON, OH 44313			ODLAND, KATHRYN P	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,514

Applicant(s)

LOB, HELKE

Examiner

Kathryn Odland

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12, 13, 20, 22 and 23 is/are rejected.
- 7) ☒ Claim(s) 5-11, 14-19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated November 26, 2003. Claims 1-23 are pending. The amendments to the specification are acknowledged.

Response to Arguments

1. Applicant's arguments, see Paper 8, filed November 26, 2003, with respect to the rejection(s) of claim(s) 1 and 23 under 35 U.S.C. 102(a and/or e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Jackson in US Patent No. 6,045,579.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 1 recites the limitation "the proximal end" and "the distal end" in lines 13 and 14. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 12 and 13 are rejected under 35 U.S.C. 102(a and/or e) as being anticipated by Jackson in US Patent No. ^{6,443,989}~~6,045,579~~.

Regarding claim 1, Jackson discloses an element for fixing in a bone having a elongate spreading body (such as 7, 8, 9) and an elongate fixing body (via 1) which **can** be introduced into aligned bores in bone fragments (note: this statement is a conditional phrase not a positive recitation) and which has a proximal first portion (denoted in the area near number 8 in figure 10), [which is to be introduced into the first bone fragment], a distal second portion (denoted in the area of 67 in figure 10), which adjoins the first portion and [which is to be introduced into the second bone fragment], and a cavity which extends substantially over its length, as seen in figure 10, wherein the fixing body (1) is adapted to be introduced completely into bores, it can be spread openly transversely with respect to its longitudinal direction by a wedge action (via 7, 8, 9) at least in the region of its two ends (note: it has not been established which ends are the intended reference) for connection with respect to [the respective bone fragment] by proximal introduction of the spreading body (7, 8, 9) into the cavity and after substantially complete introduction of the spreading body (7, 8, 9) into the cavity it is of a greater dimension transversely with respect to its longitudinal direction at the distal end (denoted as that area closes to the area of 67, in figure 10) of the second portion than at the proximal end of the second portion, characterized in that the fixing body (1) is adapted to be spread open

substantially over its entire length, as recited in column 5-7 and seen in figures such as 10. Applicant is reminded that intended use does not hold patentable weight in an apparatus claim. Furthermore, the apparatus of Jackson is capable of performing the function. Moreover, the term substantially is defined as considerable in importance, value, degree, amount, or extent by The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Synonyms are essentially, nearly, almost, all but, etc. Thus, given this broad recitation the device of Jackson does spread substantially over its entire length, especially given the spreading of the distal end, which will translate through to the proximal end.

Regarding claim 2, Jackson discloses that as applied to claim 1, as well as, a fixing body (1) that has at least two body portions (such as 15 and 16) which adjoin each other in the peripheral direction and which are connected together movably sufficiently for spreading open, as seen in figures 1-13.

Regarding claims 3 and 12, Jackson discloses that as applied to claims 1 and 2, as well as, operative surfaces of the fixing body and the spreading body, which co-operate for spreading open the fixing body, are of such a configuration that spreading of the second portion begins at the distal end of the second portion, as recited in column 5-7 and seen in figures 1-10.

Regarding claims 4 and 13, Jackson discloses that as applied to claims 3 and 12, as well as, co-operating operative surfaces of the fixing body and the spreading body that are of such a configuration that at least one first part of the first portion (that at 67 in figure 10) that is spread open before the second portion is spread open, via translated forces.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 20, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson in US Patent No. 6,443,989.

Regarding claims 20 and 22, Jackson discloses that as applied to claim 1. Moreover, it would be obvious depending on the intended use to make the item bioresorbable with a polylactide that is reinforced for it is well known in the art.

With regard to claim 23, Jackson discloses an elongate fixing body (1), sized to be introduced into the aligned bores such that a first portion (denoted by the area 8 in figure 10) defining a proximal end thereof and a second portion (denoted in the area near 67 in figure 10) defining a distal end thereof, a proximal end of the second portion adjoining a distal end of the first portion and the fixing body (1) has an operative surface defined by a cavity extending substantially

longitudinally therethrough, as recited in columns 5-7 and seen in figures 1-13; an elongate spreading body (7, 8, 9) for longitudinal introduction into the cavity at the proximal end, an operative surface of the spreading body (7, 8, 9) defined by an external surface thereof, the fixing body (7, 8, 9) operative surface and the spreading body operative surface co-acting to spread open the fixing body transversely with respect to the longitudinal direction thereof by a wedge action, such that after substantially complete introduction of the spreading body into the cavity, the second portion of the fixing body has a greater dimension transversely with respect to the longitudinal direction thereof at the distal end of the second portion than at the proximal end thereof, as seen in figure 10; and wherein the fixing body being adapted to be spread open **substantially** over its entire length, as recited in columns 5-7 and seen in figures 1-13. Although, Jackson does not disclose use for ankle fragment repair, the apparatus of Jackson, if sized is capable of performing the function. Moreover, the term substantially is defined as considerable in importance, value, degree, amount, or extent by The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Synonyms are essentially, nearly, almost, all but, etc. Thus, given this broad recitation the device of Jackson does spread substantially over its entire length, especially given the spreading of the distal end, which will translate through to the proximal end.

Allowable Subject Matter

Claims 5-11, 14-19 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 5,980,522 and US Patent No. 5,268,001.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

Henry Bennett
Supervisor/Patent Examiner
Group 3700

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